

Exhibit 53

Playing with pain killers

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ABSTRACT (ABSTRACT)

Although there are no perfect statistics on how many people misuse or abuse prescription drugs, in 1999 an estimated 4 million Americans over the age of 12 used prescription pain relievers, sedatives and stimulants for "nonmedical" reasons in the past month, with almost half saying they'd done so for the first time.

FULL TEXT

Headnote

Over the past decade, doctors have focused new energy on managing their patients' pain, and sales of prescription painkillers have tripled since 1996. For most people, these drugs are a blessing. For some, they're a nightmare. IT ALL STARTED INNOCENTLY ENOUGH. Three years ago, when Michelle Brown got pregnant, her doctor wrote her a prescription for Lortab, a potentially addictive painkiller similar to Vicodin, for relief from migraine headaches. Her migraines eventually got worse; the Lortab made her life bearable. But it had a devastating side effect: "Slowly" says Brown, who is from Sanford, Maine, "I started to get addicted." She became a classic "doctor shopper," hopping from one physician to the next to get multiple prescriptions. She discovered Percocet, and soon she was mixing Lortab with OxyContin, a new, superstrength pain-killer she got through a dealer. By early last year, Brown, 25 years old, and the mother of two small children, worked up the nerve to commit fraud. Pretending to be phoning from her doctor's office, she called her local pharmacy, read her physician's identification number off a prescription bottle and won, she says, "my key to the palace."

For millions of Americans, painkillers are a godsend. Cancer patients suffer the agony a little bit more easily. People battling severe arthritis can, for the first time, take walks and play with their grandchildren. Realizing that for years doctors neglected to include pain management in patient care, the medical establishment has, over the past decade, taken a new, more aggressive approach to treating pain. In January a national accrediting board issued new standards requiring doctors in hospitals and other facilities to treat pain as a vital sign, meaning that they must measure it and treat it as they would blood pressure or heart rate. Even Congress has gotten into the act, last fall passing a law declaring the next 10 years the "Decade of Pain Control and Research."

In this environment, pharmaceutical companies are experimenting with new formulations of painkillers, and existing painkillers themselves are more widely distributed than ever before. While the pharmaceutical market doubled to \$145 billion between 1996 and 2000, the painkiller market tripled to \$1.8 billion over the same period. Yet at the same time, the incidence of reported first-time abuse of painkillers has also surged. Many of these painkillers aren't new, and "there's not necessarily something wrong with" the increase in controlled substances, says Michael Moy in the Drug Enforcement Administration's Office of Diversion Control. "But once you put something into the food chain, someone's going to want to bite."

Although there are no perfect statistics on how many people misuse or abuse prescription drugs, in 1999 an estimated 4 million Americans over the age of 12 used prescription pain relievers, sedatives and stimulants for "nonmedical" reasons in the past month, with almost half saying they'd done so for the first time. According to the DEA, the most-abused prescription drugs include the oxycodone and hydrocodone types of painkillers, which

contain potentially addictive opioids (the two drugs differ slightly in chemical structure, but both work similarly on the body). And emergency-room data suggest that certain drugs have seen dramatic spikes in abuse in recent years. ER visits involving hydrocodone medications like Vicodin and Lortab jumped from an estimated 6,100 incidents in 1992 to more than 14,000 in 1999, oxycodone painkillers like Percodan and OxyContin rose from about 3,750 to 6,430 and the anti-anxiety drug Xanax (including generic formulations) increased from 16,500 to more than 20,500. Illegal drugs, abused in much higher numbers, also increased: cocaine from 120,000 to 169,000 and heroin and morphine from 48,000 to 84,400.

Reports of painkiller abuse from Hollywood catch the attention of the public more than any statistic ever will. In the last six months, Melanie Griffith and Matthew Perry each checked into rehab, publicly acknowledging their addiction to prescription painkillers. TV shows fill their scripts with the problem: on "ER," Dr. John Carter gets hooked on painkillers after he's stabbed, and on the new show, "The Job," Denis Leary plays a detective who takes painkillers on a stakeout. Even Homer Simpson battles a compulsion for the drugs in a season-ender where he's catapulted into a surreal celebrity existence. After looking at the data and following the news reports, the National Institute on Drug Abuse (NIDA) will announce next week a major public-health initiative about prescription-drug abuse. "Once you get into millions of people [abusing]," says Dr. Alan Leshner, NIDA's director, "you have a serious public-health issue on your hands."

Addiction to prescription drugs is not a new problem. Remember "Valley of the Dolls"? The uppers, the downers, the sleeping pills? But some of today's drugs are far more sophisticated than anything Jacqueline Susann could have envisioned. OxyContin, which hit the market in 1996, is by far the most powerful: it's a 12-hour time-release incarnation of the molecular compound oxycodone, the active ingredient in older drugs like Percodan and Percocet. Unlike drugs in the hydrocodone category, OxyContin and several other oxycodones don't contain acetaminophen, which can damage the liver in high doses and limits the extent to which those drugs can be safely used. OxyContin allows patients to swallow fewer pills, and offers pain relief three times longer than earlier versions. But when the drug is crushed and snorted, eliminating its time-release feature, it's a huge narcotic rush to the brain. "You feel vitalized, like you can do whatever you want," says Eric, 38, of Portland, Maine, who has spent as much as \$525 a week buying the drug from a street dealer. Abuse of OxyContin has gotten so bad that in some areas users are robbing pharmacies to get the drug—just last month, Hannaford, a major chain in Maine, decided that "for the safety of our associates and customers," it would no longer stock the drug on its shelves.

When it comes to prescription painkillers, there is no typical abuser. Police departments say they've seen every variety, from teenagers to stay-at-home moms to executives who started taking drugs for their tennis elbow. Particularly at risk are chronic substance abusers who may divert to prescription drugs when their preferred poisons, like heroin, run out. In Hollywood clubs, cocaine and ecstasy still dominate, one 30-year-old actor says, but people also share Vicodin, Xanax and Valium, then wash them down with alcohol. Health-care professionals, with easy access to drugs, often succumb. Among arrests in Cincinnati, which carefully tracks prescription-drug abuse, 30 percent of cases involve medical employees. Landon Gibbs, a Virginia state police officer, says his department arrested a doctor last year who would "write a prescription, drive that person to the pharmacy and then split the pills."

Prescription painkillers are appealing in part because users think of them as "safe." They're FDA approved, easy to take on the sly and don't have the same stigma as illegal drugs. Cindy Mogil started taking Valium at 20 to ease the trauma after a car accident, and "liked the feeling of euphoria." As a manager in a health clinic, she had easy access to sample pills, then found her way to Vicodin and Percodan, visiting different doctors to get her supply. "Boy, it's so easy," says Mogil, who lives in suburban Atlanta. "I'd walk in and tell them I had a migraine; that's all I had to say." Her family never questioned the pills: "They think you're taking it for medical reasons." Finally, after two decades of abuse, Mogil collapsed—her face numb, her speech slurred—and checked into rehab. "I was no better than a street addict," she says.

All pain passes through the brain. Pills like Vicodin and OxyContin lock onto a cell receptor called mu, found most prominently in the brain, spinal cord and gut. When the drug connects to the receptors in the spinal cord, pain

signals from nerves are blocked; in the brain, the receptors seem to promote an overall sense of well-being; in the gut, they have the unfortunate side effect of constipation. While any patient who takes an opioid painkiller or any other addictive drug over a long period will develop a physical dependence-meaning the body adjusts to the chemicals now swirling about and thinks that's normal-that dependence can be properly managed. When it's time to go off the drug, a good physician will taper the prescription so there's no withdrawal or rebound effect. But a genetic tendency, an underlying mental illness, a history of substance abuse or a combination of factors may lead a small group of patients to go beyond just physical dependence. They become compulsive about taking the drug, even when it threatens their health or social and professional lives.

Once you're hooked, getting more becomes an obsession. Many abusers, like Michelle Brown, become doctor shoppers. Others buy their fix on the street: one Vicodin goes for about \$6, Percocet and Percodan, up to \$8, and an 80mg OxyContin for as much as \$80. Tales of cunning and desperation abound-the weekend visits to the ER claiming a toothache, the stolen prescription pads. Dr. Sheila Calderon, an internist in Dallas, says a former employee used her name to call in a prescription for Vicodin (she was never charged). Cathy Napier, a former Percodan addict and now head of the chemical-dependency program at Presbyterian Hospital in Dallas, says she knows women who go to realestate open houses, "then go through the medicine cabinets and steal the Lortab." So who's to blame for the misuse of these drugs? Many abusers point the finger at doctors, who they say tend to prescribe medications too quickly without warning patients that certain drugs can be highly addictive. But once patients begin deceiving doctors and pharmacists by phoning in fake scripts or seeking prescriptions from multiple doctors, they become the culprits. Seventeen states currently have prescription-monitoring programs, which vary widely-some track drugs like OxyContin (a schedule II drug, deemed "high potential for abuse"), but not Vicodin (schedule III, "some potential"). But many states don't dedicate resources to full-time oversight. Nor does the DEA, which is largely watching out for abuse by health professionals. If abusers are caught, they're charged with fraud-a misdemeanor in some states and a felony in others. Brown says she is "so thankful" for the DEA agent who handled her case after a suspicious pharmacist called the police. "He knew I needed help. He told my family everything. And it just blew open from there." Now, says Brown, she's in treatment, taking methadone to ease her off her addiction and finally "learning how to live a normal life."

With all the focus on abusers, pain specialists worry that legitimate patients will suffer. Too many doctors succumb to "opiophobia," fear of prescribing muchneeded medications for appropriate patients who suffer moderate to severe pain, says Dr. Russell Portenoy, chair of pain medicine at New York's Beth Israel Medical Center. Dr. Kenneth Pollack, a pain specialist in Des Moines, Iowa, says he recently prescribed OxyContin for a woman who had suffered painful nerve tumors in her feet for 11 years and could barely stand up. Last time Pollack saw her, "she was practically in tears," he says. "She said, 'Thank you for giving me my life back'." Says David E. Joranson, director of the Pain & Policy Studies Group at the University of Wisconsin: "My fear is that some patients and doctors are going to start looking at this stuff like it's nuclear material. There is a real risk of losing recent gains made in pain management."

Pharmaceutical companies acknowledge that misuse is a problem. Pharmacia, which manufactures Xanax, says "all of our peer-group companies realize there is a potential for abuse here." They say they educate as many people as possible about the importance of taking the drug safely under a doctor's care; the drug is also marketed generically by other companies. Abbott Labs, which manufactures Vicodin, offers symposiums for prescribers and pharmacists to teach about abuse potential. And Purdue Pharma, which manufactures OxyContin, has been actively addressing the problem through education sessions and meetings with the DEA and the FDA.

Maryann Timmons, 51, says she needs her medication. After lifelong ear infections and a broken eardrum, Timmons, 51, of Concord Township, Ohio, takes Vicodin to dull the pain. Initially, she says, her doctor didn't want to prescribe the pills; he ultimately did, but told Timmons to use them sparingly because of their addictive potential. "I felt like a criminal," she says. "It shouldn't be a battle to get help with pain relief." Pain relief and criminal activity. The new challenge for doctors and publichealth officials is to provide one without advancing the other.

With JOAN RAYMOND, ELLISE PIERCE, SAM SMITH, JAY P. WAGNER, JEANNE GORDON-THOMAS and ALAN

WIRZBICKI

Sidebar

BACK STORY: A VIDEO INTERVIEW WITH CLAUDIA KALB ABOUT ADDICTION ON NEWSWEEK.MSNBC.COM

DETAILS

Subject:	Prescription drugs; Addictions; Drug abuse; Narcotics; Pharmaceutical industry; Health care; Analgesics; Physiological aspects; Consumption
Location:	United States
Product name:	OxyContin, Oxycodone, Vicodin
Publication title:	Newsweek; New York
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Number of pages:	5
Publication year:	2001
Publication date:	Apr 9, 2001
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